

REMARKS

Entry of the foregoing amendments, and reexamination and reconsideration of the subject application, pursuant to and consistent with 37 C.F.R. § 1.104 and § 1.112, and in light of the following remarks, are respectfully requested.

Amendments

The specification and claim 28 have been amended as suggested by the examiner.

Independent claims 1, 20, and 32 have been amended to recite a surgical kit for *hemiarthroplasty* as opposed to the total hip replacements in the cited art, and is supported through the specification (e.g., the abstract).

Independent claims 1 and 28, and new claim 35, recite the femoral head as having a radius of curvature determined with reference to the weight of the patient for whom the kit is intended (e.g., page 3, first paragraph).

In claim 20, “reamed” has been inserted before “acetabulum.”

Claims 4, 5, 21, 22, 33, and 34 have been amended to recite that the membrane or multiple spacers are provided on the surface of the femoral head or the reamed acetabulum, support for which is at least at page 4 (ln. 5-6) and page 5 (ln. 16-17).

Claim 32 has been amended to clarify the claimed method of making.

Oath/Declaration

A substitute declaration of the inventors is submitted herewith.

Claim Objections

The objections are believed obviated by the present amendments.

Rejections under 35 U.S.C. §112, second paragraph.

The present amendments are believed to overcome these rejections.

Rejections under 35 U.S.C. §102

1. The rejection of claims 1-3 as anticipated by Anderson is respectfully traversed. The specification makes clear that the radii of curvature of the femoral head and the complementary reamer should be determined with reference to the weight of the patient, and the rejected claim includes this particular language. As described and

claimed, this structure is chosen such that liquid between the femoral head and socket is subjected to a hydrostatic pressure in the range 0.01-5MPa, effective for stimulating the formation of new cartilage between the socket and the femoral head. Anderson teaches using a femoral head adapted merely to fit a reamed socket (col. 5, ln. 17-24; paragraph bridging cols. 6 and 7; and col. 7, ln. 62-65). Nowhere does Anderson describe or disclose the claimed radius of curvature relationship to a patient's weight. There is no support for alleging that the "appropriately" sized and shaped elements in Anderson describe, or even suggest, the claimed invention.

For example, a relatively heavy patient may naturally have an undersized femoral head, and so the present claim would provide a larger than existing prosthetic femoral head to achieve the desired pressure range. Anderson does not describe the claimed structure, and so this rejection should be withdrawn.

2. The rejection of claims 1, 5, 7, 13, 15, and 17 as anticipated by Maumy (*et al.*) is respectfully traversed. Maumy is directed to total hip replacement, whereas the rejected claims have been amended to recite *hemiarthroplasty*, and the reference also lacks the aforementioned claimed radius of curvature relationship to a patient's weight. Further, the rejected claims now require spacers "on the surface of the femoral head or the reamed acetabulum" whereas Maumy discloses the elements 40 and 41 on the outside of the prosthetic acetabulum. This rejection should now be withdrawn.

3. The rejection of claims 20, 22, 24, and 27 as anticipated by Maumy is respectfully traversed. As noted, these claims are now directed to *hemiarthroplasty*. Further, the rejection does not address the radius of curvature relationship and the particular size limitation particularly recited, and so all of the claimed features are not present in the cited reference.

4. The rejection of claim 28 as anticipated by Anderson is respectfully traversed. The rejection fails to provide any support for the alleged inherency of the recited pressure range, and is requested to provide a citation in support thereof if this rejection is maintained. 37 C.F.R. §1.104(d). As noted above, Applicants have disclosed that the surface relationship between the femoral head and the socket effects the hydrostatic pressure of liquid between the femoral head and socket, and that the structure is achieved with reference to a patient's weight . Anderson does not disclose or suggest a method using a structure where the "femoral head ha[s] a radius of curvature

determined with reference to the weight of the patient for whom the surgical kit is intended.” Nothing in Anderson suggests adapting the contact area between the femoral head and acetabulum; they are only sized so that they fit (col. 5, ln. 17-24), suggesting they are designed to mate perfectly complementary and not “closely complementary” as claimed to allow fluid in the space to be subjected to the recited pressure range.

Ishihara only describe growth within an intact vertebral disk and give no information regarding cartilage growth in the environment of a reamed joint surface.

Accordingly, this rejection may now be withdrawn.

5. The rejection of claims 32-33 as anticipated by Harris (*et al.*) is respectfully traversed as these claims recite a *hemiarthroplasty* environment and Harris is directed to a total hip replacement with a prosthetic acetabulum, so this rejection should now also be withdrawn.

Rejections under 35 U.S.C. §103

1. The rejection of claims 4, 6, 8-12, 14, and 16 as obvious over Anderson in view of Brown (*et al.*) is respectfully traversed. As noted above, Anderson lacks all of the elements of claim 1. Brown is directed to growing tissue *in vitro* (*i.e.*, *ex vivo*) and requires a cycle loading of the growth substrate, and says nothing about how a structure with a particular orientation of nutrient flow to a substrate that is cyclically deformed could be incorporated into the environment of *arthroplasty*. Anderson appears to have no disclosure of a membrane or film, and discloses bone growth only using bone chips where the stem protrudes (col. 5, ln. 58-72, and Figs. 9-13). Using the Brown device without a flowing nutrient and cyclical deformation is directly contrary to the teachings of Brown. The rejected claims reciting a membrane on the surface of the femoral head or the reamed acetabulum would not have been obvious from these two disclosures.

2. The rejection of claim 18 as obvious over Anderson in view of Harris is respectfully traversed. As noted above, Anderson does not anticipate claim 1, from which claim 18 depends. Further, the rejection misconstrues the claim by using “clearance” as equivalent to the claimed “radius of curvature”, which it is not. The distance between the head and cup is independent of the radius of curvature, especially when the Harris liner is apparently the important consideration in that reference. Rather, Fig. 8 shows a perfect mating and no room for fluid. There is no clearance, no

free space, in Harris as alleged in the rejection, and so Harris teaches away from providing a claimed radius of curvature to allow a fluid space. Accordingly, this rejection should be withdrawn.

3. The rejection of claim 19 as obvious over the combination of Mosseri and Averill (*et al.*) is respectfully traversed. Averill does not disclose inwardly and outwardly facing teeth as alleged in the rejection (citing to col. 3, ln. 35-45), but rather the possibility of a single reamer having two different diameters, so that successively greater diameters are used (col. 7, ln. 12-22). The art does not suggest the double-acting reamer of the present invention. In fact, the guide arm 7 in Mosseri would obstruct contact between the bone and cutting heads on the same surface as the guide arm, and so the purported combination is unworkable and the rejection cannot stand.

4. The rejection of claim 20 as obvious over Anderson and Harris is respectfully traversed for the reasons given above in paragraph 2 with respect to claim 18.

5. The rejection of claims 21, 23, 25, and 26 as obvious over Anderson in view of Harris and Brown is respectfully traversed. These claims all depend effectively from claim 20, which is just shown not to be obvious from the combination of Anderson and Harris, and Brown is directed to a particular deformable and fed device for tissue growth that has not been shown adaptable or even considered by the cited references.

6. The rejections of claims 29 and 30 as obvious over Mosseri and Averill are traversed for the reasons given above in paragraph 3; namely, that none of the references disclose or suggest a reamer having “cutting teeth facing not only outwardly toward the socket surface but also inwardly toward the ball surface.” Averill does not show a reamer having inwardly and outwardly facing teeth as those terms are used in the claim with reference to “the socket ... [and] ... the ball surface.”

7. The rejection of claim 31 as obvious over Anderson is respectfully traversed for the reasons given above as to claims 1 and 28. The rejection alleges nothing more than an “obvious to try” argument without any suggestion or motivation in the area of hemiarthroplasty why the claimed method, with the relationship between pressure and contact area, would have been obvious when none of these parameters are mentioned

in the art. On what basis, solely from Anderson, would one recognize that a hydrostatic pressure should be present, in what range it should be, and how it should be achieved?

8. The rejection of claim 34 as obvious over the combination of Harris and Babalola is respectfully traversed. As noted, Harris is directed to a total hip replacement. The allegation that "hip prostheses" is the field to which both references pertain is immaterial to the claimed hemiarthroplasty because that procedure is different than total hip replacement, and so "hip prostheses" is too broad with respect to the claimed invention and includes art that does not appreciate the problems to which the present invention is directed.

Conclusion

In light of the foregoing, entry of the amendments, and further and favorable action, in the form of a notice of allowance, are believed to be next in order, and such actions are earnestly solicited.